CHAPTER 5

PROBABILISTIC RISK ASSESSMENT AND PRELIMINARY REMEDIATION GOALS

5.0 INTRODUCTION

According to the National Contingency Plan (NCP) (U.S. EPA, 1990a, 40CFR §300.430(d)(4)), risk assessment and risk management decision making go hand-in-hand: data from the remedial investigation are used to characterize risk, and results of the baseline risk assessment help to establish acceptable exposure levels for use in developing remedial alternatives. In practice, risk managers may identify two major objectives of risk assessment: (1) to determine if remediation is necessary (i.e., *Is there unacceptable risk at the site?*); and (2) if remediation is necessary, to determine a preliminary remediation goal (PRG) (i.e., *What chemical concentrations would result in a risk estimate that will be adequately protective of human health and the environment?*). The answer to the first question *(is there unacceptable risk?*) depends upon a number of factors, including the measured or estimated concentration levels of contaminants in site media, and takes uncertainty in the measurements into account. In contrast, the answer to the second question (*what is the PRG needed to achieve a specified level of protection?*) does not necessarily depend on any knowledge of the actual level or pattern of site-specific concentration data, and does not necessarily depend on the uncertainty in site concentration data. Thus, while exposure point concentrations (EPCs) and PRGs are closely related to each other, they have important differences (see Section 5.1 for further elaboration on EPCs and PRGs).

Once a risk manager has selected a PRG at a site, determining whether a particular area meets or will meet the PRG requires careful comparison of site data with the PRG, including a consideration of the uncertainty in the site data. For a further discussion on variability and uncertainty in the concentration term, readers are urged to consult Appendix C in this guidance.

EXHIBIT 5-1

SUMMARIES OF SOME KEY TERMS

Preliminary Remediation Goal (PRG) - initially developed chemical concentration for an environmental medium that is expected to be protective of human health and ecosystems. PRGs may be developed based on applicable or relevant and appropriate requirements, or exposure scenarios evaluated prior to or as a result of the baseline risk assessment. (U.S. EPA, 1991a).

Generic PRG - a chemical concentration protective of human health developed prior to the baseline risk assessment that uses default exposure assumptions representing common exposure scenarios, e.g., Region 3 risk-based concentrations (RBCs) or Region 9 PRGs.

Site-specific PRG - site-specific chemical concentration, protective of human health and ecosystems, based on exposure scenarios in the baseline risk assessment. Generally calculated for the various exposure scenarios considered in the baseline risk assessment.

Remediation Goals (RG) - site-specific chemical concentration, protective of human health and ecosystems, chosen by the risk manager as appropriate for a likely land use scenario.

Remediation Action Level (RAL) - the "not-to-exceed" level; a concentration such that remediation of all concentrations above this level in an exposure unit lowers the EPC sufficiently to achieve a target risk level. The RAL will depend on the mean, variance, and sample size of the concentrations within an exposure unit as well as considerations of short-term effects of the chemicals of concern.

Cleanup Level (Final Remediation Level) - chemical concentration chosen by the risk manager after considering both RGs and the nine remedy selection criteria of the NCP (U.S. EPA, 1990a). Also referred to as Final Remediation Levels (U.S. EPA, 1991a), chemical-specific cleanup levels are documented in the Record of Decision (ROD). A cleanup level may differ from a PRG because risk managers may consider details of the site-specific exposure, various uncertainties in the risk estimate, and implementation issues (e.g., the technical feasibility of achieving the PRG).

EXHIBIT 5-2

DEFINITIONS FOR CHAPTER 5

95% UCL for mean - The one-sided 95% upper confidence limit for a population mean; if a sample of size (*n*) was repeatedly drawn from the population, the 95% UCL will equal or exceed the true population mean 95% of the time. It is a measure of uncertainty in the mean, not to be confused with the 95th percentile (see below), which is a measure of variability. As sample size increases, the difference between the UCL for the mean and the true mean decreases, while the 95th percentile of the distribution remains relatively unchanged.

95th Percentile -The number in a distribution that is greater than 95% of the other values of the distribution, and less than 5%of the values. When estimated from a sample, this quantity may be equal to an observed value, or interpolated from among two values.

Applicable or Relevant and Appropriate Requirements (ARARs) - Federal or state environmental standards; the NCP states that ARARs should be considered in determining remediation goals. ARARs may be selected as site-specific cleanup levels.

Backcalculation - A method of calculating a PRG that involves algebraic rearrangement of the risk equation to solve for concentration as a function of risk, exposure, and toxicity.

Bootstrap Methods - Parametric and non-parametric methods for estimating confidence intervals for a statistic by resampling directly from the data set with replacement.

Coverage - Confidence intervals are expected to enclose a true but unknown parameter according to a specified probability, such as 90% or 95%. This is the expected coverage of the confidence interval, given a specified significance level (alpha). The difference between the expected coverage and the actual coverage is one metric for evaluating statistical methods that yield different confidence intervals.

Exposure Point Concentration (EPC) - The average chemical concentration to which receptors are exposed within an exposure unit. Estimates of the EPC represent the concentration term used in exposure assessment.

Exposure Unit (EU) - For Superfund risk assessment, the geographical area about which a receptor moves and contacts a contaminated medium during the period of the exposure duration.

Forward Calculation - A method of calculating a risk estimate that involves the standard arrangement of the risk equation to solve for risk as a function of concentration, exposure, and toxicity.

Iterative Reduction (IR) - A method of calculating a PRG that involves successively lowering the concentration term until the calculated risk is acceptable. This method can be applied to any medium.

Iterative Truncation (IT) - A method of calculating a PRG that involves developing an expression for the concentration term in which higher values of concentration are removed or "truncated" to reduce the maximum concentration, and re-calculating risks associated with the reduced concentration. The method may be repeated with consecutively lower truncation limits until risk is acceptable.

Land Method - The conventional method for calculating uncertainty in the mean concentration (e.g., 95% UCL) when the sample data are obtained from a lognormal distribution (U.S. EPA, 1992).

Maximum Detected Concentration (MDC) - The maximum concentration detected in a sample.

True Mean Concentration - The actual average concentration in an exposure unit. Even with extensive sampling, the true mean cannot be known. Only an estimate of the true mean is possible. A greater number of representative samples increases confidence that the estimate of the mean more closely represents the true mean.

Two Office of Solid Waste and Emergency Response (OSWER) guidance documents in preparation: (1) *Draft Guidance on Calculation of Upper Confidence Limits for Exposure Point Concentrations at Superfund Sites* (U.S. EPA, 2001a), and (2) *Draft Guidance on Surface Soil Cleanup at Superfund Sites: Applying Cleanup Levels* (U.S. EPA, 2001b), also address topics related to the calculation of EPCs and comparison of those EPCs to a PRG.

In practice, calculations of risks, given concentration data, are commonly referred to as "forward calculations", while calculations of PRGs, based on chosen target risk levels, are referred to as "back-calculations". This terminology reflects the algebraic rearrangement of the standard risk equation needed to solve for the concentration term when point estimates are used to characterize exposure and toxicity input variables. For probabilistic risk assessment (PRA), the process for developing a PRG can be more complex. This chapter presents methods and recommendations for developing site-specific PRGs within the framework of PRA.

Are there different types of PRGs?

Generic PRGs have been developed for some chemicals and exposure media using point estimates based on standard default exposure assumptions (e.g., U.S. EPA, 1991b) and toxicity criteria available in the Integrated Risk Information System (IRIS) or Health Effects Assessment Summary Table(s) (HEAST) or from Environmental Protection Agency's (EPA's) National Center for Environmental Assessment. Soil Screening Guidance levels, Region 9's PRG table and Region 3's Risk Based Concentrations (RBCs) table are examples of generic point estimate PRGs. Generic PRGs are often used for screening chemicals of potential concern in Data Evaluation and Hazard Identification steps of the risk assessment process.

☞ *There is a clear distinction between generic PRGs, site-specific PRGs, remediation goals (RGs), and cleanup levels. The focus of this chapter is on site-specific PRGs.*

At this time, EPA does not recommend the use of PRA to develop generic PRGs. Until the science and policy decisions associated with the use of default assumptions in PRA have evolved, generic PRGs should only be developed from point estimate methods, as was done in the examples listed above.

As indicated in Exhibit 5-1, site-specific PRGs generally are developed after the baseline risk assessment. However, during the feasibility study or even later in the Superfund process, the methods described in this chapter may be used to modify cleanup levels at the discretion of the risk manager. However, it is generally not appropriate to use PRA for modifying cleanup levels during the feasibility study if PRA was not used in the baseline risk assessment.

☞ *Risk-based PRGs are initial guidelines and do not represent final cleanup levels.*

Only after appropriate analysis in the remedial investigation/feasibility study (RI/FS), consideration of public comments, and issuance of the record of decision (ROD) does a RG become a final cleanup level. A cleanup level may differ from a RG because risk managers may consider various uncertainties in the risk estimate. While the two main criteria for determining a cleanup level are: (1) protection of human health and the environment, and (2) compliance with applicable or relevant and appropriate requirements (ARARs), a cleanup level may differ from the RG because of modifying criteria, such as feasibility, permanence, state and community

acceptance, and cost effectiveness. These and other factors are reflected in the nine evaluation criteria outlined in the NCP (U.S. EPA, 1990a; 40CFR §300.430(e)(9)(iii)) (see Chapter 1, Exhibit 1-2).

This chapter and Appendix C provide a comprehensive description of the issues associated with developing site-specific PRGs with both point estimate and probabilistic approaches, including the use of geostatistics. Because methods for calculating a 95% upper confidence limit for the mean (95% UCL) are discussed fully in the *Draft Guidance on Calculation of Upper Confidence Limits for Exposure Point Concentrations at Superfund Sites* (U.S. EPA, 2001a) and *Draft Guidance on Surface Soil Cleanup at Superfund Sites: Applying Cleanup Levels* (U.S. EPA, 2001b), they are covered only briefly in this guidance. In general, this chapter, Appendix C, and the Superfund guidance under development should be consulted by risk assessors when developing site-specific PRGs.

5.1 GENERAL CONCEPTS REGARDING EPCS AND PRGS

PRGs developed from point estimate risk assessments and PRAs will be discussed in this section to compare and contrast the two approaches. The PRG is a special case of the concentration term (or EPC) in the risk equation. The intent of the EPC is to represent the average chemical concentration in an environmental medium in an exposure unit (EU) (i.e., the area throughout which a receptor moves for the duration of exposure). The EPC should be determined for individual EUs within a site. Because an EPC is calculated from a sample, there is uncertainty that the sample mean equals the true mean concentration within the EU; therefore, to account for associated uncertainty, the 95% upper confidence limit for the mean (95% UCL) is generally used for Superfund risk assessments (U.S. EPA, 1992). For both point estimate and probabilistic approaches, the PRG is an assumed value of the EPC that yields a risk estimate that is at or below an acceptable risk level.

> ☞ *The EPC usually represents the average concentration within the EU estimated from a sample; the PRG usually represents the average concentration within the EU that corresponds to an acceptable level of risk.*

The PRG may be thought of as a goal for the post-remediation EPC (see Section 5.1.2). Specifically, after remediation is completed, the average concentration (or the 95% UCL used as a measure of uncertainty in the average) for the EU should be sufficiently low to be protective of human health and the ecosystem. While the methods used to calculate the pre- and post-remediation EPC may differ, the interpretation of the EPC remains constant. For example, if the 95% UCL is used to represent the EPC before remediation, then the EPC following remediation (e.g., the PRG) should also represent a 95% UCL (Bowers et al., 1996).

Risk assessors may consider both variability and uncertainty in the development of an EPC. The calculation of a 95% UCL generally requires knowledge of not only chemical concentration measurements within the EU but also the receptor's behavior. Relevant information may include the variability in concentrations in the given sample, the sampling locations, and variability in the movement and activity patterns of receptors within the EU. A discussion of spatial and temporal variability associated with characterizing contamination in different exposure media is presented in Appendix C, and important sources of uncertainty in the EPC are discussed in Section 5.1.1.

For all risk assessments, chemical concentration measurements should be collected in a manner that is consistent with an understanding of both the source of contamination and the definition of the exposure unit. An investment of time and resources should be made in planning, scoping, and problem formulation. Part of this investment is to follow the Data Quality Objectives (DQO) process to obtain samples appropriate for the risk

assessment and sufficient to support the remedial decision (U.S. EPA, 1993, 1994, 2000). Using new methods of sample collection and analysis such as dynamic workplans and real-time analysis may enable risk managers to get the most "bang for the buck" from the resources available for site characterization. Information about these methods and the DQO process is available from EPA's Office of Emergency and Remedial Response (U.S. EPA, 2001c) and Technology Innovation Office (U.S. EPA, 2001d, 2001e). The world wide web address is http://clu-in.org/char1_edu.cfm#syst_plan.

5.1.1 SOURCES OF UNCERTAINTY IN THE EPC

The 95% UCL is generally used as the EPC to represent uncertainty in the mean concentration in both the central tendency exposure (CTE) and reasonable maximum exposure (RME) risk estimates for Superfund (U.S. EPA, 1992). Similarly, in PRA, a probability distribution for uncertainty may be used in a two-dimensional Monte Carlo analysis (2-D MCA) simulation (see Appendix D) to represent a source of uncertainty in the EPC. There are numerous potential sources of uncertainty in the estimate of the true mean concentration within the EU. The sources of uncertainty when the EPC is expressed as either a single number or a distribution are the same and can be grouped into the following four broad categories:

(1) ***Uncertainty in the sample data.*** A limited number of measurements in the sample are used to make inferences about the EPC and the spatial distribution of concentrations at a site. Uncertainties may arise from many factors, including both sampling variability and measurement error. As the number of samples increases, the uncertainty generally decreases (e.g., more information will be available to characterize the spatial distribution and variation in concentration). In point estimate risk assessments, the 95% UCL is generally used as the EPC to account for the uncertainty in estimating the average concentration within an EU.

(2) ***Uncertainty about the location of the EU.*** When the size of a receptor's EU is less than the size of the site, the placement of the EU may be a source of uncertainty, especially when the contamination is distributed unevenly across the site and the PRA includes exposure scenarios for future land uses.

(3) ***Uncertainty in the behavior of the receptor.*** Even in the case of extremely well characterized sites, it remains uncertain whether the receptor will contact the environmental medium in a temporal and/or spatial distribution that can be adequately represented by the environmental samples collected.

(4) ***Uncertainty in chemical concentrations over time.*** The concentration in a given medium may undergo temporal changes, which may introduce uncertainty in estimates of a long-term average. Examples include the movement or attenuation of a solvent plume in groundwater; aerobic or anaerobic degradation; the change in the average concentration in a fish population due to changes in population dynamics; and the mixing of surface and subsurface soil over time.

A lack of knowledge in all four categories may be considered when selecting approaches to quantify uncertainty in the concentration term. One of the first steps in quantifying uncertainty is to define the EU, or the geographical area in which individual receptors are randomly exposed for a relevant exposure duration. Depending on the receptor's movement and activities, an EU may be as small as a child's play area (e.g., sandbox) or as large as the foraging area of an upper trophic level animal predator (e.g., an entire military base). The relationship between the size of the EU, the movements of the target receptor, and health endpoint of concern (i.e., acute or chronic) may dictate the appropriate use of sample data in developing an EPC. One of the assumptions generally made for the concentration term in Superfund risk assessment is that receptors contact all

parts of an EU at random, and that measurements are obtained from a simple (or stratified) random sample. If an individual is randomly exposed within the same EU over a long period of time, the most appropriate metric for the EPC would be the true (but unknown) population mean of the concentrations within the EU (e.g., 95% UCL).

Often, the scale of the EU will be different (smaller or larger) than the scale of the sample data. For example, an ecological receptor population may have a small home range relative to the size of the entire site, or the endpoint of concern may be acute toxicity, requiring an evaluation of a short-term exposure scenario. If the receptors are not expected to contact all parts of the site with equal probability, then the EU may be redefined so that only a subset of the data collected for site characterization are used to estimate the EPC. In addition, the location of the EU may be unspecified within the site because there may be multiple areas that provide suitable habitat for the receptor population. Departing from the assumption of random exposure within one unique geographic area presents an additional challenge to estimating an EPC. In some cases, it may be informative to develop multiple estimates of the EPC in a PRA. By treating the EPC as a random variable, risk assessors can explore the effect of uncertainty in the location of the EU. A variety of modeling approaches are available to calculate an EPC (e.g., arithmetic mean, or 95% UCL) based on the spatial variability in chemical concentrations measured over an area larger than the EU. Methods such as geostatistics (see Section 5.5.2 and Appendix D), Microexposure Event Modeling (MEE) (see Appendix D), and random walk scenarios (Hope, 2000, 2001) may be used to quantify both the spatial and temporal variability in exposure to varying concentrations. Using these methods, risk assessors may redefine the EU to be more representative of the random movement of the receptor during the period of exposure. Because these modeling approaches may be considered more advanced methods for quantifying the EPC, they are generally considered in Tier 3 of the PRA process (see Chapter 2).

5.1.2 Pre- and Post-Remediation Exposure Point Concentrations

The differences between pre- and post-remediation EPCs are discussed below. In general, both estimates of the EPC are based on the same concepts regarding the exposed population and the definition of the EU. However, the post-remediation EPC will tend to yield lower estimates of (post-remediation) risk and can require more advanced methods for calculating uncertainty (e.g., 95% UCL).

The pre-remediation EPC is determined based on existing site sampling at the time of the remedial investigation, prior to remediation. By contrast, the post-remediation EPC generally is determined based on a prediction of site conditions after remediation. For example, in surface soil, the post-remediation EPC can be determined by substituting the nondetect level (generally, half the laboratory reporting limit) for some of the high concentrations in the sample and recalculating the EPC. The underlying assumption in calculating a post-remediation EPC is that remediation will have sufficiently reduced the chemical concentrations at the site, and the risk existing after remediation is complete will be equal to or less than the target risk level of concern.

The preceding discussion is most applicable to surface soil PRGs. In general, compared with other exposure media (e.g., groundwater, air), surface soil is stationary with relatively constant chemical concentrations within an EU. For other environmental media, more complex approaches may be needed to estimate the post-remediation EPC. Modeling of the remediation process may introduce additional uncertainty not encountered in risk estimates based on the pre-remediation EPC.

5.1.3 REMEDIATION ACTION LEVELS (RALS) AND 95% UCL CALCULATION METHODS

The EPC should incorporate knowledge about the spatial distribution of contamination, the behavior of the receptor, the location of the EU, land use, and other factors. These factors affect both the numerical value of an EPC and uncertainty associated with this estimate. In many cases, it is presumed factors associated with land use will not change after remediation.

The remediation action level (RAL) is the maximum concentration that may be left in place at any location within an EU such that the average concentration (or 95% UCL as a measure of the average) will not present a risk above levels of concern. This RAL may be considered a "not-to-exceed" threshold or action level for the purposes of site remediation. Using surface soil as an example, areas within the EU that have concentrations greater than the RAL may be excavated and replaced with clean fill (e.g., nondetect surrogate values). To obtain a post-remediation EPC, the 95% UCL is calculated after substituting the surrogate nondetect value for all measurements located within the EU that are greater than the RAL.

When appropriate, the same statistical method of uncertainty should be used to estimate UCLs for both the pre- and post-remediation EPCs. However, in some instances, the method used for calculating the pre-remediation EPC will be inappropriate for calculating the post-remediation EPC, because the distribution of contaminant concentration will have changed. For example, pre-remediation site sampling may suggest that variability in concentrations can be reasonably characterized by a lognormal distribution, which would support the use of the Land method for estimating the 95% UCL. The post-remediation site conditions, however, may reflect a mixture of clean fill and contamination, resulting in a poor fit to a lognormal distribution (see Figure 5-3, Section 5.5.3). In this case, the Land method would not be appropriate. Because of the difference in the statistical distribution of concentration measurements used to estimate the pre-remediation EPC and post-remediation EPC, a non-parametric (i.e., distribution free) method should be considered for calculating uncertainty in the average concentrations in both pre- and post-remediation scenarios. In general, when the method used to calculate the 95% UCL for a post-remediation scenario is different than that of the pre-remediation scenario, the 95% UCL for the pre-remediation scenario should be recalculated with the post-remediation method. Results of this change in methodology can be presented as part of a quantitative uncertainty analysis. Specifically, this recalculation will allow for an evaluation of the effect that a RAL has on the confidence interval for the mean. The discordance between pre- and post-remediation distributions can be expected to increase as the degree of remediation needed to achieve a target risk level of concern increases.

In general, risk assessors should be aware of the practical and statistical issues associated with the various methods of calculating the 95% UCL, and the application of these methods to both the pre- and post-remediation concentration distribution. Different methods can yield very different confidence intervals, some of which are expected to yield more accurate coverage (i.e., likelihood that the confidence interval includes the parameter) depending on characteristics of the underlying distribution of concentrations, such as distribution shape, sample size, and variance (Gilbert, 1987; Hall, 1988). Information about a variety of parametric and non-parametric methods, such as bootstrap resampling, can be found in *The Lognormal Distribution in Environmental Applications* (U.S. EPA, 1997), *Estimating EPCs When the Distribution is Neither Normal nor Lognormal* (Schulz and Griffin, 1999) and a Superfund guidance document currently under development, *Draft Guidance on Calculation of Upper Confidence Limits for Exposure Point Concentrations at Superfund Sites* (U.S. EPA, 2001a).

5.1.4 CONSIDERATION OF RISK FROM ACUTE TOXICITY

Sometimes a risk assessment will need to address more than one health endpoint of concern (e.g., cancer and noncancer). The RAL should be sufficiently low so that it is simultaneously protective of each endpoint of concern. Generally, when acute toxicity is a concern, the long-term average concentration across the entire EU may not be the appropriate metric for assessing risks. For example, a single episode of a child ingesting a handful of soil containing malathion may result in an acute toxic effect to that child. Therefore, the RAL must not only be low enough to reduce the post-remediation EPC to acceptable long-term average levels, but also low enough that acute toxicity will not be an issue. This consideration applies to both point estimate and probabilistic estimates of PRGs.

☞ *For consideration of acute toxicity, the risk assessor should consult, as appropriate, with a toxicologist in the development of RALs.*

For a small number of chemicals, toxicity values have been determined based on acute effects (e.g., nitrate in drinking water). However, at present, EPA does not have acute toxicity criteria or guidance on acute toxicity applied to the RAL. Hence, consultation with a toxicologist is vital.

5.1.5 CHARACTERIZATION OF UNCERTAINTY IN THE EPC: POINT ESTIMATES AND DISTRIBUTIONS

In point estimate risk assessments, the 95% UCL is typically used to characterize uncertainty in the EPC (U.S. EPA, 1992). In PRA, either a point estimate (e.g., 95% UCL) or a probability distribution may be used to characterize uncertainty in the concentration term. The probability distribution may characterize either variability or uncertainty. The terms probability distribution for variability (PDFv) and probability distribution for uncertainty (PDFu) can be used to distinguish between probability distributions for variability and uncertainty, respectively.

The decision to use a point estimate, PDFv, or PDFu, as the input for the concentration term in a Monte Carlo model will depend on the goals of the Monte Carlo simulation, as determined by the tiered process (see Chapter 2). If the goal is to characterize variability in risk, in general, a one-dimensional Monte Carlo analysis (1-D MCA) will be used and the appropriate input for the concentration term will be a point estimate that characterizes uncertainty in the mean concentration within the EU. As explained in Section 5.1.1, risk assessors will need to consider the relationship between the size of the EU, the movements of the target receptor, and health endpoint of concern (i.e., acute or chronic) to determine how to use the available sample data to define the EPC. A PDFu is typically not an appropriate choice for the concentration term in a 1-D MCA when the goal is to characterize variability in risk. Mixing of a PDFu for the concentration term with PDFv's for other exposure variables in 1-D MCA would yield a single risk distribution from which the relative contributions of variability and uncertainty could not be evaluated. Use of a PDFu for the concentration term may be considered in 2-D MCA simulations (see Appendix D), where the goal may be to characterize both variability and uncertainty in risk.

When the sample size is small and the variance is large, the 95% UCL may exceed the maximum detected concentration (MDC). In such a case, the MDC is generally used to estimate the EPC, although the true mean may still be higher than this maximum value (U.S. EPA, 1992). For poorly characterized sites, there may be considerable uncertainty that site remediation will be sufficient to reduce the 95% UCL to a health-protective level. Poor site characterization may provide an impetus for the risk manager to opt for a more health-protective remedial alternative or to collect additional data.

To ensure that actual cleanup based on a RAL is protective generally requires post-remediation confirmation sampling. This step in the risk management process is emphasized further in Section 5.8 on measurement of attainment.

5.1.6 MULTIPLE CHEMICALS

Developing PRGs for multiple chemicals in one or more environmental media is particularly challenging. When multiple chemicals are present, the total risk level should be considered for regulatory purposes with each chemical contributing a portion of the total risk. This issue is quite complex and usually will affect both the calculation of the risk and development of site-specific PRGs. Chemicals may exhibit different spatial and temporal variability within the EU. Fate and transport characteristics may vary between chemicals as well as between different areas of the site. Co-located sampling, or geostatistical techniques (e.g., co-kriging) may provide insights regarding relationships in spatial patterns for different chemicals (see Appendices C and D) and the corresponding exposures for receptors.

5.2 WHEN TO USE PRA FOR DEVELOPING PRGS

Because point estimate risk assessments and PRA employ different approaches to characterize variability and uncertainty, the resulting RME risk estimates and calculations of PRGs are often different. The magnitude of the difference can depend on many factors, including the number of input variables described with probability distributions in the PRA, the choice of distributions used to characterize variability or uncertainty (especially for those variables that are highly ranked in a sensitivity analysis), the percentile of the probability distribution that corresponds with RME point estimate for each input variable, and the choice of percentile from the PRA used to represent the RME risk (e.g., 95th percentile). Since the results of a point estimate approach and PRA can be expected to differ, but the magnitude of the difference is not known *a priori*, this can present a challenge in deciding whether or not to conduct a PRA to develop a PRG. The potential advantages and disadvantages of both the point estimate approach and the PRA can be factored into the decision (see Chapter 1, Exhibits 1-6 and 1-7).

In general, PRA may be appropriate for developing site-specific PRGs in cases where PRA has also been used to estimate site-specific risks. As indicated by the tiered approach (see Chapter 2), if the risk manager determines that quantifying variability and uncertainty may enhance risk management decision making, PRA may be warranted. If a PRA is feasible, the risk manager should proceed to Tier 2 and employ PRA to complete the RI/FS process. Usually, embedded in a site-specific PRG are all of the exposure assumptions and toxicity metrics used in the risk assessment. Hence, introducing the use of PRA for PRGs in the feasibility study (or any time after the remedial investigation and baseline risk assessment are complete) would, in effect, undermine the tiered approach.

> ☞ *If only point estimates were used in the risk assessment, probabilistic methods should not be used for PRG development.*

If additional data have been collected to conduct PRA, the point estimate risk assessment should be revisited with the new data as well. As discussed in Chapter 2, a point estimate risk assessment (Tier 1) should always accompany a PRA. PRA is intended to enhance risk management decision making, and should not be viewed as a substitute for point estimate approaches. Using the tiered approach, a risk assessor can determine the appropriate level of complexity that is supported by the available information to conduct the risk assessment and to calculate a PRG.

5.3 METHODS FOR DEVELOPING PRGS

Risk assessors may use PRA to quantify sources of uncertainty and variability in the calculation of PRGs as well as risks. Two of the common methods for calculating PRGs in PRA include: (1) backcalculation (see Section 5.4), which is equivalent in concept to the point estimate calculation of a PRG; and (2) iterative forward calculation methods, including iterative reduction and iterative truncation (see Section 5.5). Backcalculation can be used in PRA when the target risk and concentration terms are expressed as point estimates. Iterative methods can be more involved, but unlike backcalculation, there are no constraints on their application to PRA. The two approaches yield the same result when the same assumptions are used in the risk assessment.

5.4 BACKCALCULATION

Traditionally, risk is calculated as a function of multiple exposure variables, including the concentration term, and toxicity value (Equation 5-1). If one or more of the exposure variables is described by a PDF, a Monte Carlo simulation will yield a distribution for risk (see Chapter 1).

Backcalculation methods can be envisioned as setting a target risk level (e.g., RME risk equal to 10^{-6} or Hazard Index equal to 1) and then algebraically reversing the risk equation to solve for the concentration term (Equation 5-2). A Monte Carlo simulation using Equation 5-2 will yield a distribution of concentrations that reflects the combination of distributions from all other exposure variables.

$$\frac{C \times IR \times EF \times ED}{BW \times AT} = Intake$$

$$Intake \times Toxicity = Risk \qquad \text{Equation 5-1}$$

$$C \times V = Risk$$

$$C = Risk \times V^{-1} \qquad \text{Equation 5-2}$$

where,

Toxicity	=	toxicity term representing either the cancer slope factor (CSF) or reference dose (1/RfD) for the chemical in the exposure medium
C	=	concentration term
V	=	algebraic combination of the toxicity term with all exposure variables except *C*
IR	=	ingestion or inhalation rate
AT	=	averaging time
BW	=	body weight
ED	=	exposure duration
EF	=	exposure frequency

This calculation produces a distribution of PRGs that represents the same sources of variability as a forward calculation of risk. Each percentile of the PRG distribution (i.e., the α percentile) corresponds to the 1-α percentile from the distribution of risk estimates. For example, if the 95th percentile of the distribution of risk estimates was chosen to represent the RME individual, the 5th percentile (1-0.95=0.05) would be the corresponding concentration value from the distribution of PRGs (Bowers, 1999). The correspondence between the risk distribution and the PRG distribution is intuitive—just as selecting a higher percentile on the risk distribution is more protective, a lower percentile on the PRG distribution is more protective. The RME range

for the risk distribution 90th to 99.9th percentile is analogous to an RME range for the PRG distribution of 0.1st to 10th percentile.

Backcalculation has been a familiar method of developing PRGs and may be appropriate in some situations for the sake of clarity and transparency due to the general understanding of this method among risk assessment practitioners. Once a backcalculation has been performed to determine a PRG, the PRG should be used as the concentration term in a forward calculation to ensure that the risk at the PRG is acceptable.

5.4.1 DIFFICULTIES WITH BACKCALCULATION

There are limitations in the use of backcalculation in PRA (Ferson, 1996). Simple rearrangement of Equation 5-1 does not suffice when the variable (i.e., the concentration or risk term) that is backcalculated is represented by a probability distribution (Burmaster et al., 1995; Ferson, 1996). The difficulty for PRA arises because each risk estimate from an MCA that uses the familiar "forward-facing" risk equation represents a combination of random values selected from the input distributions. Therefore, the output can be considered conditional on all of the inputs. Rearranging the risk equation does not maintain the same conditional probabilities; therefore, the distribution for risk estimated as a function of the distribution for concentration in Equation 5-1 does not return the same distribution for concentration when applied in Equation 5-2. While there are techniques that can maintain the dependencies and correlations between exposure factors when the risk equation is rearranged (e.g., deconvolution), they are complex and beyond the scope of this guidance.

Backcalculation methods may also be difficult to implement in situations in which complex fate-and-transport considerations are present. Leaching of soil contamination to groundwater, bioconcentration of chemicals at higher trophic levels, and other multimedia processes that result in exposure via several environmental media are situations in which backcalculation may not be useful. Note that these difficulties are not unique to backcalculation. Uncertainty in fate-and-transport considerations makes any type of PRG determination challenging.

Further, the backcalculation approach only provides information on the EPC that corresponds to a risk level of concern; it does not specify an RAL that would achieve this EPC. For example, when a risk equation is algebraically solved for concentration (see Equation 5-2), a PRG is developed without a corresponding RAL. Thus, there is no information associated with the PRG value to indicate the highest concentration in the EU that must be removed so that the average concentration (or 95% UCL) within the EU is at or below the PRG. Hence, additional efforts are needed. In addition, post-remediation concentrations may need to satisfy more than one regulatory constraint. For example, the average (or 95% UCL) concentration within an EU may need to be less than a concentration associated with chronic toxicity or cancer and simultaneously, the RAL concentration may need to be less than a concentration that might cause acute toxicity.

In spite of these caveats, backcalculation methods may be appropriate for some sites. For example, when the target risk is specified by a single numerical value and the risk manager has chosen a percentile of variability to represent the RME individual, then a backcalculated PRG can be derived from a PRA.

Although backcalculation methods may be appropriate for some sites, risk assessors should be familiar with their limitations. Because of these limitations, this guidance recommends iterative forward calculations as the primary method for calculating PRGs when performing a PRA. Iterative methods avoid difficulties associated with applying MCA to a backcalculation, and can provide more information for the risk manager.

5.5 ITERATIVE METHODS

Iterative methods simply involve calculating risk with the "forward-facing" equation (see Equation 5-1) a number of times (iteratively) using progressively lower values for the concentration term until the risk is sufficiently protective. This iterative method has also been called the "repeated runs" method. Note that iterative methods for calculating a PRG are not uniquely applicable to PRA. Iterative methods also may be used to develop PRGs in point estimate risk assessments.

☞ *EPA recommends iterative simulations as a general approach for calculating PRGs from probabilistic risk assessments.*

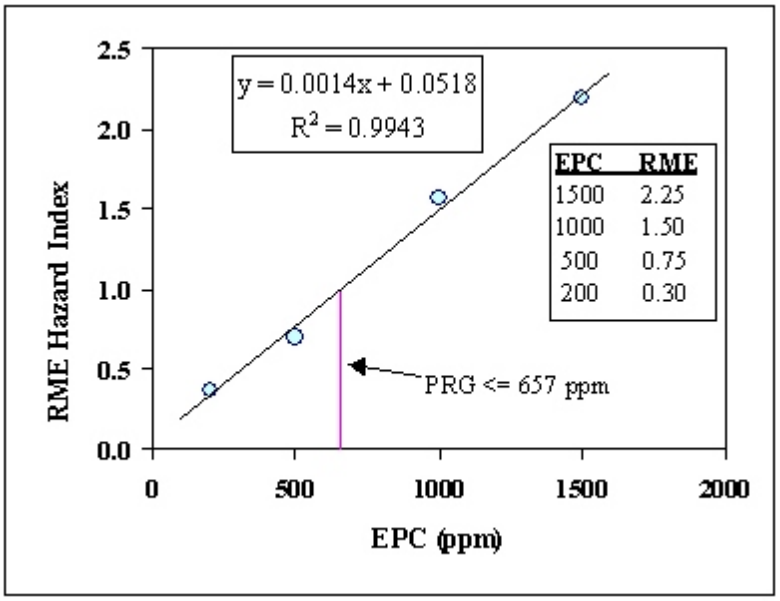


Figure 5-1. A hypothetical example of the use of iterative methods to determine the EPC that corresponds with a target RME Hazard Index (HI) of 1.0. Assume that the EPC is represented by the 95% UCL and the RME HI is the 95th percentile of the output distribution. In this case, four separate Monte Carlo simulations were run with iteratively decreasing values for the EPC. The least-squares, best-fit line to these four data points suggest that a reasonable PRG would be approximately 660 ppm.

Most often, iterative forward calculations are performed using a systematic trial-and-error method until the percentile of variability in risk chosen to represent the RME individual is at or below acceptable risk levels. Sometimes, a short cut can be used to reduce the number of simulations needed with the trial-and-error method. If successive "guesses" of the EPC are plotted with the corresponding risk estimate, the exact solution can be determined from the best-fit line, thereby significantly reducing the effort required to implement this method. An example is given in Figure 5-1. For many risk equations, the relationship between the EPC and the RME risk will be approximately linear. Nevertheless, the final estimate of the EPC should be checked by running another simulation for risk with this estimate.

A possible and significant advantage of iterative forward calculations over back-calculations is that the method is intuitive and yields a distribution of risks rather than a distribution of PRGs (as with a back-calculation method). The distribution of risks will be more familiar to the public and other stakeholders, and thus, both the method and the resulting output may be easier to communicate to senior level managers and stakeholders (see Chapter 6).

Two general types of iterative methods are described in more detail in Sections 5.5.1 and 5.5.2. The main difference between the methods is in the interpretation of the concentration term that is being reduced. With iterative reduction, the concentration is assumed to be the post-remediation EPC, whereas with iterative truncation, it represents the RAL needed to achieve a post-remediation EPC.

5.5.1 ITERATIVE REDUCTION

Iterative reduction can be applied to any medium. Generally, a point estimate representing the EPC (e.g., 95% UCL) is successively lowered, each time repeating the Monte Carlo simulation of variability in risk. When the EPC is reduced until the endpoint of concern (e.g., RME risk corresponding to the 95th percentile) is at or below an acceptable level of risk, the PRG is set at the corresponding EPC. The goal is to identify the point estimate that corresponds to a target risk level. Note that the PRG is not the same as the RAL. The RAL is the maximum concentration that may be left in place within an EU to achieve the PRG.

The concentration at which the risk is acceptable defines the PRG. Therefore, the PRG bears the same uncertainties as the EPC. For example, assume that a risk assessor examined the carcinogenic effects from chronic consumption of a chemical in groundwater, then the exposure unit may be determined by the long-term average concentration at any well that potentially draws drinking water from the contaminated groundwater. Uncertainty in the long-term average concentration can reflect a number of factors that contribute to spatial and temporal variability, including the direction of groundwater flow, natural attenuation, and other fate and transport variables. Remediation by a pump-and-treat system for a prolonged period of time may be used to lower the concentrations at the wells. Even though the remediation strategy may be complicated by spatial and temporal variability, iterative reduction can be used to establish a PRG. A remediation strategy may be considered a potential candidate if it can achieve the PRG by reducing the average concentration at each of the well locations. The concept of "hot-spot" removal, or truncation of the highest concentrations first, would not be an option under this scenario (see Section 5.5.2).

5.5.2 ITERATIVE TRUNCATION

Iterative truncation is a method of calculating a PRG that involves developing an expression for the concentration term in which higher values of concentration are removed or "truncated" to reduce the maximum concentration. These higher values are replaced by the surrogate nondetect value. The risk is recalculated for each successive reduction in the highest value. The method is repeated with consecutively lower truncation limits until risk is acceptable.

Iterative truncation is most applicable to surface soil cleanup as the spatial variability over time is minimal compared to other media (e.g., surface water). With each iteration of the risk equation (e.g., Equation 5-1), the highest concentration value is truncated corresponding to a different RAL. In this way a"not-to-exceed" level is specified and the PRG is recalculated the same way in each iteration. The process continues until the risk distribution yields risk estimates at or below the level of concern.

Iterative truncation can be applied to either the empirical distribution function (EDF) for the concentration term, or a fitted distribution for variability in concentrations within the EU. Applied to the EDF, the maximum detected concentration within the EU is replaced with a surrogate value for a nondetect (e.g., half the reporting limit or the background value for some chemicals), and the EPC (e.g., 95% UCL) is recalculated for this altered data set. If this new EPC yields unacceptable risk, then the two highest detected concentrations are replaced by the nondetect value and the EPC is recalculated. In the third iteration, the three highest detections are replaced, and so on, until the target risk level is achieved. Alternatively, the sample data may be fit to a probability distribution for variability, and the process would be repeated with decreasing values in the high-end tail of the continuous distribution.

When the concentration term is a distribution representing uncertainty in the mean concentration, then, similar to the recalculation of the point estimate 95% UCL described above, this distribution of uncertainty in the mean concentration should be determined anew each time a datum is replaced with the nondetect value.

When a distribution of variability in concentration is used for the EPC, for example, in an ecological risk assessment where sampling may be sparse relative to the foraging area of a small home range receptor (see Appendix C), then the distribution developed in an identical way with the high values replaced by the surrogate nondetect value should be used in the iterative determination of a PRG.

The decision to apply iterative truncation should be made after considering a variety of characteristics of the sample data and post-remediation scenario (see Exhibit 5-3). For example, small sample size may result in high uncertainty in the 95% UCL, thereby limiting the use of iterative truncation. Quantitative criteria regarding these factors are not provided in this guidance given that the level of certainty required for decision making will vary on a case-by-case basis. Use of geostatistical methods (Appendices C and D) may aid in interpreting site data or improving sampling design. Geostatistics is capable of describing the spatial distribution of a contaminant in a quantitative fashion. These methods establish a correspondence between the actual sampling locations and the locations a receptor would be expected to frequent. Additionally, it enables the estimation of concentrations in unsampled locations. Hence, for determination of concentrations at specific locations at a site or within EUs of various sizes and shapes, geostatistics may provide an invaluable tool. Geostatistics has applications both to developing the EPC and PRG and has been recommended and used at some sites for characterization of soil and groundwater contamination (U.S. EPA, 1990b, 1991c).

Although the consideration and use of geostatistics is encouraged, a full consideration of geostatistics is beyond the scope of this guidance. Those interested in greater detail than provided in Appendices C and D are urged to consult the Superfund guidance document currently under development, *Draft Guidance on Surface Soil Cleanup at Superfund Sites: Applying Cleanup Levels* (U.S. EPA, 2001b), for additional discussion of how geostatistics can be used to quantify the concentration term or the PRG.

Generally, iterative truncation methods fail to produce adequate cleanup strategies when site

EXHIBIT 5-3

CRITERIA FOR ITERATIVE TRUNCATION

1. **Sample size (*n*) is sufficient.** Small sample sizes lead to large estimates of uncertainty in the concentration term. Small sample size may cause the risk assessor to overlook some sources of uncertainty.

2. **Concentration distribution is not highly skewed.** A highly skewed distribution may yield unreliable estimates of uncertainty, especially for small sample sizes.

3. **Sampling design yields a representative distribution of measurements within the exposure unit.** Simple random sampling may fail to represent a patchy spatial distribution of contaminants. Similarly, hotspot (e.g., cluster) sampling may fail to represent random movement of receptors. To evaluate potential biases in sampling, analyses with both standard statistical methods and geostatistical methods may be required.

4. **Assumptions about the post-remedial distribution of concentration are reasonable.** If these assumptions are shown to be incorrect by subsequent sampling events, the process for developing a PRG may need to be repeated and additional remedial activities may be required.

characterization is incomplete. This problem, however, is not specific to PRA. Both point estimate and probabilistic methods are sensitive to poor site characterization.

Risk assessors should realize that application of iterative truncation may result in areas on-site that have concentrations higher than the PRG. This is because the PRG will reflect an average concentration (or 95% UCL) from a distribution of concentrations in which the maximum is truncated at the RAL. For example, Figure 5-3 (see Section 5.5.3) shows how the concentration distribution can be truncated at an RAL, while still leaving behind concentrations greater than the PRG.

5.5.3 EXAMPLE OF ITERATIVE METHODS

The iterative truncation method is easiest to think about with regard to soil cleanup when contaminated soil is removed and replaced with clean fill soil. This replacement would reduce both the mean and 95% UCL. In most cases, risk assessors may assume that the concentrations of chemicals in clean fill soil can be represented by the surrogate nondetect value (e.g., half the detection limit). Alternatively, the fill may be sampled so that the measured concentrations in the fill dirt may be used to calculate the post-remediation concentration term. Generally, metals and other inorganic chemicals will be present in clean fill, albeit at lower concentrations than on site.

A simple example using the 95% UCL as a point estimate for the EPC is given in Exhibit 5-4. In this example, background concentrations of chemical X were very low and hence, the fill was assumed to have a concentration of half the detection limit. The risk management objective is to identify a PRG in which the 95th percentile risk estimate is below 1E-04 and to determine the RAL necessary to achieve this PRG. This example illustrates how iterative truncation is applied to the empirical distribution function, rather than fitting the concentrations to a parametric distribution.

Assume that iterative reduction of the 95% UCL demonstrated that a post-remediation EPC of no greater than 33 mg/kg is needed to achieve a RME risk of 1E-04. What is the RAL that yields this EPC? The risk assessor recognizes that the post-remediation concentration distribution is very often a mixed distribution, consisting of a group of nondetect values and a truncated parametric distribution. Because of the complex nature of mixed distributions (Roeder, 1994), non-parametric methods for calculating the 95% UCL of the arithmetic mean (e.g., bootstrap resampling) were determined to be appropriate (U.S. EPA, 1997; Section 5.1.3).

EXHIBIT 5-4

EXAMPLE OF ITERATIVE METHODS

Scoping and Problem Formulation

Chromium contamination was present at a 12-acre industrial facility. In scoping and problem formulation, all stakeholders agreed that the facility would maintain itself and the current land use would continue into the foreseeable future. Most of the facility area was maintained as green space and as a buffer with the surrounding community. Surrounding the facility to the fence line were lawns and ornamental shrubs tended by landscape workers. These landscape workers were considered to be the high risk group as they would move freely and randomly over the entire area of the facility outside the buildings. Hence, the landscape workers would be exposed to an average concentration over the entire area of the facility outside the buildings. The management of the facility was very cooperative and concerned about their workers. Nonetheless, the facility management did not wish to bear more cost than necessary.

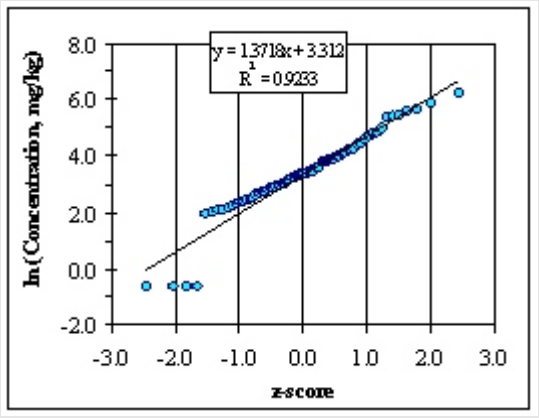
Site Characterization - Soil Sample (n=70)

Seventy surface soil samples were obtained using a sampling grid placed over all 12 acres. Five or six sampling locations were placed in each acre. None of the samples was composited. The grid-based sampling permits a rough estimation of the percentage of the site that would need active remediation. The detection limit for the chromium was 1 mg/kg. Four of the samples were nondetects. Sampling results are shown in Table 5-1. Although the samples from the site appeared to occur in a lognormal distribution (Figure 5-2), the presumed post-remediation distribution would be a mixed distribution, consisting of a truncated lognormal distribution and a group of data at the surrogate nondetect value.

Table 5-1. Soil sample (n=70) (mg/kg).

0.5	9.7	16.2	25.1	34.0	54.1	120.6
0.5	10.6	17.1	25.4	34.0	57.8	122.2
0.5	10.8	17.4	26.4	36.5	60.2	140.7
0.5	11.0	17.9	26.9	43.3	65.7	211.9
6.8	11.8	18.4	27.1	43.3	66.1	224.1
7.2	12.0	18.6	28.2	45.3	71.8	235.6
7.8	13.7	19.7	28.3	46.4	82.7	266.8
8.0	13.9	19.8	30.3	48.2	84.7	284.0
8.2	14.7	22.0	30.9	49.3	98.1	361.2
9.3	15.0	22.8	31.1	52.6	107.7	486.6

Figure 5-2. Lognormal probability plot of soil concentrations, including 4 nondetects.



In this example, a series of iterative truncations showed that removal of all sample results greater than 100 mg/kg (n=11) and replacement of these with the nondetect surrogate of 0.5 mg/kg yielded a 95% UCL of 33 mg/kg and RME risk below 1E-04. Table 5-2 summarizes the results of the calculations for the three conditions: (1) pre-remediation concentrations; (2) post-remediation concentrations using iterative truncation to achieve an RAL of 100 mg/kg; and (3) post-remediation concentrations assuming the 95% UCL calculated is used as the RAL. Note that if the PRG of 33 mg/kg was applied as a "not-to-exceed" level (i.e., RAL), the resulting remediation effort would increase from 15 to 40% of the site, yielding a 95% UCL of 14 mg/kg. While this would be a protective decision, other information was used to support the selection of the second scenario instead. A toxicologist was consulted, who indicated that acute exposure to the workers at levels of 100 mg/kg would not present a health risk. To build additional protectiveness into the remedy, the management also indicated scheduling for the landscape workers would be performed so the areas tended would be rotated among all the workers.

Table 5-2. Pre- and Post-Remediation EPCs (95% UCLs) for Chemical X in Surface Soil Samples.

Remediation Scenario	RAL (mg/kg)	EPC (mg/kg) 95% UCL	Percent of Site to be Remediated
1. Pre-remediation	NA	93	NA
2. Post-remediation using the PRG as the 95% UCL	100	33	15%
3. Post-remediation using the PRG as the RAL (i.e., "not-to-exceed")	33	14	40%

NA=not applicable for a pre-remediation scenario.

Figure 5-3 shows a conceptual framework for considering the post-remediation distribution as a mixture between a group of nondetects and a distribution of contamination truncated at the RAL. Prior to remediation, the EPC exceeds a level that would be protective of human health and ecosystems. If the high-end soil concentrations are removed and the soil is replaced with clean fill, the resulting distribution will be bimodal, with one peak occurring at the nondetect concentration, and the second occurring near the mean of the post-remediation distribution.

5.5.4 Multiple Exposure units and Iterative Methods

When multiple EUs are present at the site, there may be a small number of samples within a given EU and the uncertainty in the concentration term generally will be large. It may be possible to use knowledge of the mechanism of how the contamination occurred along with spatial patterns in the sampling results in other nearby EUs to quantify uncertainty. Geostatistical techniques for estimating the mean concentration may provide useful insights into the importance of accounting for spatial relationships among the sample data. Appendix C also provides a discussion of the situation of multiple EUs within a larger site.

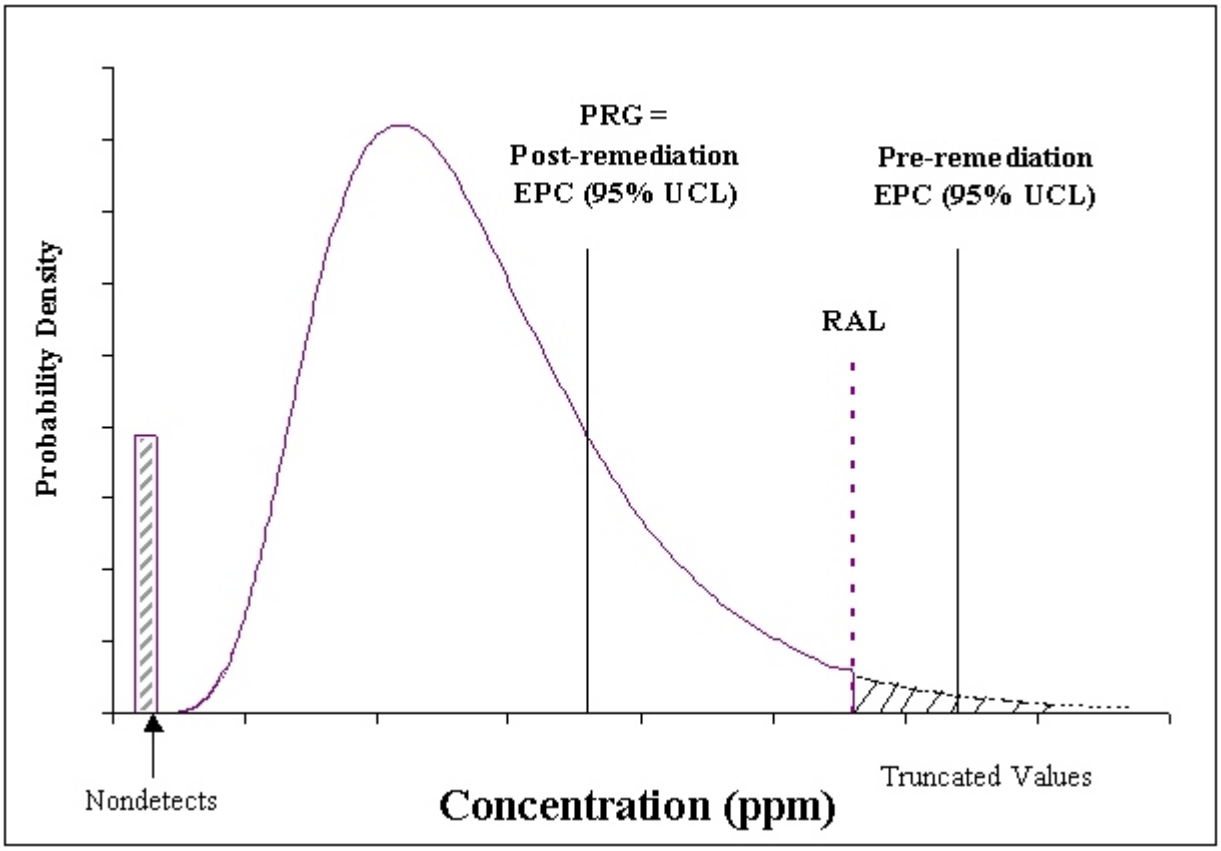


Figure 5-3. Hypothetical example of a mixed, bimodal distribution that represents a combination of the pre-remediation distribution truncated at the remediation action level (RAL) and a uniform distribution representing clean fill at the surrogate nondetect concentration. Shaded portions represent equal areas. In this example, the PRG is defined by the post-remediation EPC (95% UCL).

5.6 PRGs FOR GROUNDWATER

For some chemicals encountered at hazardous waste sites, chemical-specific ARARs may exist, and may be considered as PRGs. ARARs may be selected as site-specific cleanup levels. The maximum contaminant levels of the Safe Drinking Water Act are examples of ARARs.

> ☞ *For groundwater contamination, ARARs should be applied as RALs if they are protective.*

Of course, for cases in which an ARAR is less protective than a remediation goal determined from a risk assessment, then a risk-based PRG may be developed in accordance with the NCP (U.S. EPA, 1990a).

As an exposure medium, groundwater is the opposite of soil in that groundwater is not static, and receptors are usually exposed at one location (i.e., the well head). Often, a single well can be considered the EU when assessing risks associated with either the residential or industrial/occupational scenarios. The EPC may

still reflect the concept of averaging over a long time period (e.g., years) due to potential changes in concentrations in well water over time. For example, chemical fate and transport modeling may suggest that concentrations are decreasing over time. Similarly, there may be temporal and spatial variability depending on the seasonal fluctuations of the water table. Ideally, the risk assessment would focus on individuals who may be exposed at locations nearest to the center of the contaminant plume, where concentrations are likely to be highest (Freeze and Cherry, 1979; Sposito, et al., 1986).

Because of the uncertainty in the movement of groundwater and the necessity of sampling the medium at fixed locations, identifying a meaningful RAL needed to achieve a given PRG is difficult. In most cases, ARARs will be applicable as RALs or "not-to-exceed" levels.

5.7 PRGs FOR OTHER CONTAMINATED MEDIA

Iterative truncation techniques are generally applied to a static medium, such as soil, rather than dynamic or fluid media such as water and air. This is simply because it is difficult to design a method that will selectively remove high concentrations from a fluid medium. Iterative reduction may be more relevant than iterative truncation when an RAL cannot be developed. These issues are discussed below with respect to sediment, surface water, and fish.

Sediment

Sediment may be transported over time more readily than soils. If it can be assumed that the sediment remains in place, then iterative truncation techniques may be applied. However, at some sites, sediment may be considered a fluid medium. For example, sediment may be resuspended by the movement of water craft, waves, changing tides, or erosion. Similarly, the depth of the contaminated sediment may change over time as new layers of sediment are deposited above more contaminated sediment.

Exhibit 5-5 gives an example of the use of iterative truncation to evaluate alternative RALs for sediment of a lake contaminated by pesticide runoff. In this example, the RAL is related to both the ecological endpoint of concern (i.e., reduction in reproductive success of mammalian omnivores at the lake) and the fraction of areal extent of the lake that would require remediation at that RAL.

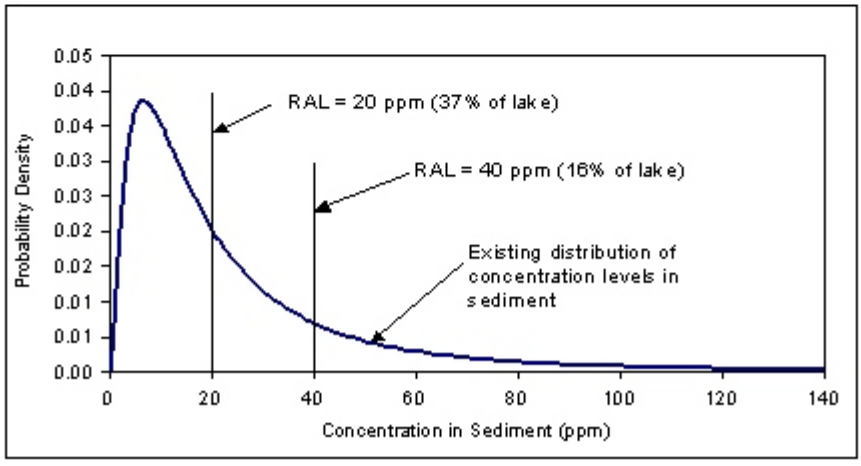
EXHIBIT 5-5

EVALUATION OF ALTERNATIVE RALS USING ITERATIVE TRUNCATION

Risks to a population of mammalian omnivores residing near a lake contaminated with pesticide "X" were judged to be sufficiently high that a reduction in population number over time was expected (see Chapter 4, Exhibit 4-12). The primary reservoir of pesticide X in the lake is sediment. The BTAG committee decided to use the iterative truncation method to estimate the beneficial effects of a series of different Remedial Action Levels (RALs). PRA was used to predict the distribution of responses (percent reduction in population success) and the areal extent of the lake requiring remediation as a function of RAL. The results are summarized below.

RAL in Sediment	Reduction in Reproductive Success			Fraction of Lake
	Mean	90th	95th	
None	8.9%	31%	59%	0%
100 ppm	7.6%	24%	48%	3%
80 ppm	7.0%	27%	45%	5%
60 ppm	5.9%	18%	36%	8%
40 ppm	4.4%	12%	26%	16%
20 ppm	1.9%	4.7%	10%	37%

The BTAG reviewed these results and concluded that while an RAL of 20 ppm would be needed to provide nearly complete protection of the exposed population, an RAL of 40 ppm would provide a good reduction in effect level while tending to minimize the areal extent of the lake that required remediation, which in turn would tend to minimize disturbance of the ecosystem during remediation. Based on this, the risk manager identified 40 ppm as the RAL and initiated a feasibility study to investigate ways of achieving this objective.



Biota (Fish, Aquatic Invertebrates, Plants)

Biota, such as fish, aquatic invertebrates, and plants can serve as bioindicators or indirect estimators of contamination in other exposure media that would be targets for remediation. The concentration of chemicals fish may reflect a combination of exposures via sediment, the water column, and food source (e.g., prey). Therefore, the use of bioindicators to develop PRGs in other media introduces a sources of uncertainty. If there is a high correlation between concentrations in fish and sediment, then sediment concentrations may be considered when developing PRGs to protect the receptor population. The EU, in this case, is the area where the angler population, or ecological predator population, harvests fish. However, in risk assessments that include a fish ingestion exposure pathway, there may be high uncertainty about the true concentration term. Concentrations may be affected by many factors, including changes in the fish population and changes in fish preferences, which may be difficult to address in risk assessments. The choice of fish species consumed by a given individual may also affect the concentration term.

Fish population studies and fate and transport considerations of the contaminants may indicate if and when a fish population will reach a calculated cleanup level. For many sites, it may be difficult to obtain this level of site-specific data due to resource and time constraints.

Although remediation may not immediately reduce contaminant concentrations in biota, the determination of a cleanup level can serve as a target for any future decline in concentrations. In general, iterative reduction methods are applicable for developing PRGs to protect aquatic ecosystems; however, under some conditions iterative truncation may also be used. For example, if contamination is correlated to relatively static sediment, and the home-range of the fish is relatively small (e.g., nonmigratory) then iterative truncation may be applicable.

Surface Water

The development of PRGs for surface water is also difficult with iterative truncation. For fluid media (e.g., groundwater or surface water), iterative reduction can be performed using a range of EPCs to determine a PRG with acceptable risk at the target RME percentile.

5.8 MEASUREMENT OF ATTAINMENT

The NCP (U.S. EPA, 1990a) provides for continued monitoring for groundwater cleanups to ensure attainment of the remedial action objectives. In addition, it is common practice among remedial project managers to conduct confirmation sampling after completing a remedy for soil contamination. However, completion of the remedial action according to this strategy does not necessarily mean that risks within EUs at the site have been reduced to levels specified in the ROD. The degree of uncertainty about whether the remedial action at the site has achieved the cleanup level should determine whether confirmation sampling is warranted. In general, confirmation sampling following cleanup activities is recommended. Sampling after the remedial investigation is complete may show additional areas needing remediation (i.e., where additional contamination exists).

If additional sampling is conducted after the remedial investigation, the concentration term and corresponding estimates of risk should be recalculated. The PRG developed in the remedial investigation may not be health-protective in light of the additional contamination. The same concepts that relate the concentration term to the PRG should be applied in this situation.

Confirmation sampling activities are included in remedial design/remedial action plans to ensure the remedy is successful. In addition, the five-year review presents a second opportunity to ensure that any contamination left on site does not pose an unacceptable risk.

☞ *If confirmation sampling indicates an insufficient reduction in risk, a more extensive remediation effort may be needed. Possible reasons for not achieving remedial action objectives can include inadequate site characterization or the discovery of unknown contamination.*

For post-remediation sampling, the DQO process should generally be followed. If the post-remediation risk associated with the confirmation sample indicates risk exceeds a level of concern, then additional remediation may be warranted.

5.9 SUMMARY OF RECOMMENDED METHODS

Table 5-3 summarizes the possible methods for developing PRGs for various environmental media. It should be noted that iterative reduction (IR) can be used in all cases, whereas iterative truncation (IT) is limited to situations where the highest concentrations can be identified and removed. Backcalculation may be applicable in all cases, but because of caveats noted in Section 5.4.1, iterative approaches are generally recommended in this document.

Table 5-3. Summary of Potential Methods for PRG Development by Environmental Medium.

Potential Exposure Medium	Back-calculation	Iterative Reduction (IR)	Iterative Truncation (IT)	Explanations for IT
Soil	X	X	X	Applicable if soil is relatively fixed.
Sediment	X	X	X	Applicable if sediment is relatively fixed. In some situations, sediment transport may be a better assumption due to current velocity, tides, resuspension, etc.
Biota (Fish, Aquatic Invertebrates, Plants) - bioindicators of contamination in sediment	X	X	SA	Depends on home-range of fish relative to the scale of the sampling design. If contamination is correlated to relatively static sediment, and the home-range of the fish is relatively small (e.g., non-migratory) then IT may be applicable.
Surface Water	X	X	NA	Not applicable as surface water is a fluid medium.
Groundwater (GW)	X	X	NA	Not applicable as GW is a fluid medium. Generally, ARARs must also be satisfied.
Home-grown produce, milk, livestock, other food items	X	X	SA	Depends on relative contributions of soil uptake (applicable) vs. foliar deposition (not applicable).

X=applicable
NA=not applicable
SA=sometimes applicable

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